

Phoenix WinNonlin Validation Suite 7.0

Validation Made Easy

As required by US FDA's 21 CFR Part 11, International Conference on Harmonization of Technical Requirements (ICH), EudraLex Annex 11, and other regulatory agency guidance documents, computer systems used in the pharmaceutical industry, and output from software used in regulatory submissions, must be validated to assure proper performance. This necessitates companies to invest significant time and resources to manually write and perform the validation steps used in software execution.

The Phoenix® WinNonlin® Validation Suite™ 7.0 is a desktop application that provides objective evidence of Phoenix WinNonlin 7.0 functionality and streamlines the validation process through the use of automated tests accessed through a graphical user interface and validation document templates.

Obtain automated WinNonlin 7.0 validation test results in days rather than weeks

- Automatic execution of detailed test scripts ensure rapid, consistent and error-free testing of WinNonlin 7.0 functionality, lowering costs of your validation project
- Test scripts and/or test plans can be customized to obtain full control of the testing process
- Provides documentation of activities by automatically generating a Validation Run Report
- Compares output to standard, verified, known results
- Results of comparisons reported in Microsoft® Word
- Allows rapid development of validation documentation using the included validation life cycle templates

Validation Life Cycle Templates included in Phoenix WinNonlin Validation Suite 7.0

- Validation Plan
- Phoenix WinNonlin Requirements Specification
- Test Plan
- Phoenix WinNonlin Traceability Matrix
- Validation Summary Report

Functions Tested by Phoenix WinNonlin Validation Suite 7.0

General Functionality

- Installation Qualification (IQ)
- Plotting
- Plot export
- Data formatting and precision
- Data manipulation
- Data dependencies
- Data export and import
- Inclusion/exclusion

Models

- NCA
- PK, PD, and PK/PD
- Indirect response
- Michaelis-Menten
- Simulation

Table Templates

- Verifies WinNonlin table templates 1-8 function correctly
- Tests creation of legacy WinNonlin table template 9

Toolbox Functions

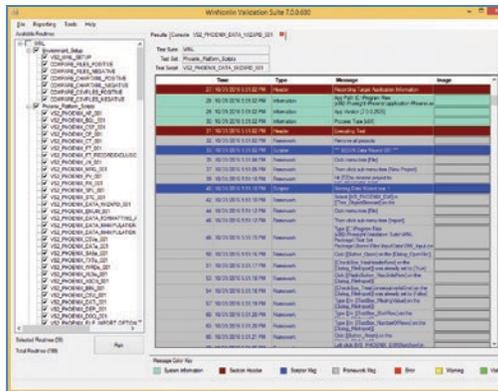
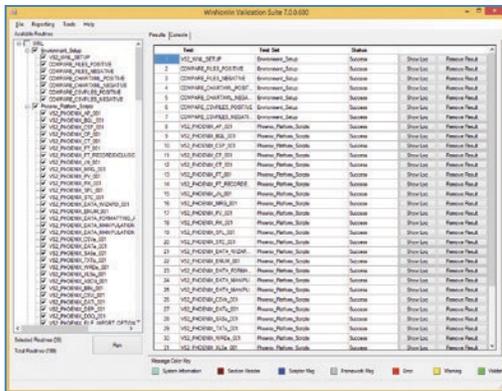
- Crossover design
- Deconvolution
- Descriptive statistics
- Linear mixed effects
- Bioequivalence
- Semicompartmental modeling
- Nonparametric superposition

WinNonlin Examples

- Runs modeling and NCA examples from Phoenix WinNonlin Examples Guide

Automatic execution of WinNonlin Validation Suite 7.0 scripts

Validation Suite 7.0 provides nearly 200 test scripts that efficiently test and document your on-site testing activities by automatically operating Phoenix WinNonlin 7.0 to generate output, comparing output to standard known results, and reporting results in a Microsoft Word Run Report.



Successful Execution of WinNonlin Validation Suite 7.0 Scripts

The graphical user interface allows you to easily drill down into the Validation Run Report to assess outcome of all test scripts.

Step-by-step Results from Executing an Individual Script

Obtain detailed reports generated from specific individual test scripts.

Use Phoenix WinNonlin Validation Suite 7.0 to ensure compliance under the following conditions:

- Upon a new installation of Phoenix WinNonlin 7.0
- After upgrade to Phoenix WinNonlin 7.0 from a previous version of Phoenix WinNonlin
- Upon re-installation of Phoenix WinNonlin 7.0
- If a change to the implemented Phoenix WinNonlin 7.0 system is determined as part of the internal change control process to impact the validation status of the system

Are you ready to streamline your Phoenix WinNonlin 7.0 validation testing?

Contact us at sales@certara.com to learn how you can automate your validation testing to gain efficiency and productivity.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

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